510(k) Summary K122742

In accordance with Title 21 of the Code of Federal Regulations, Part 807, and in particular 21 CFR §807.92, the following summary of information is provided:

A. Submitted by:

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Date Prepared: November 6, 2012

B. Device Name

Trade or Proprietary Name:	*NuVasive® Bendini® Spinal Rod Bending System*
Common or Usual Name:	Stereotaxic Instrument
Classification Name:	Instrument, Stereotaxic
Device Class:	Class II
Classification:	§882.4560
Product Code:	OLO

C. Predicate Devices

The subject *Bendini Spinal Rod Bending System* is substantially equivalent to the following devices:

- K111811 – Bendini Spinal Rod Bending System
- K033621 – Northern Digital Inc. (NDI) Passive Spheres

D. Device Description

The *NuVasive Bendini Spinal Rod Bending System* consists of instruments (manufactured from stainless steel and polycarbonate) and software components that are used to locate spinal implant system instrumentation (screws, hooks), determine their relative location to one another, and generate bend instructions that are used along with the Bendini bender to shape a rod for use in spinal surgery applications.

The Bendini System consists of three main components:

1) ***IR Stylus*** – composed of a sterile handle with integrated IR markers, and non-sterile shaft options (solid or offset), that helps obtain the location of the implants,
2) ***Software*** – provided on a Bendini System control unit, converts the implant locations to a series of bend instructions, and
3) ***Mechanical Rod Bender*** – tool used by the surgeon to execute the bend instructions.

E. Intended Use

The *Bendini Spinal Rod Bending System* is used to locate spinal implant system instrumentation (screws, hooks) to determine their relative location to one another to generate bend instructions to shape a spinal rod. A surgeon is able to use those instructions and bend a

rod using the Bendini Bender, a mechanical rod bender.

F. Technological Characteristics

As was established in this submission, the subject *Bendini Spinal Rod Bending System* is substantially equivalent to a predicate device cleared by the FDA for commercial distribution in the United States.

The *Bendini Spinal Rod Bending System* shares the following components with the predicate device: a computer with touch screen display, a six (6) DOF optical localizer system, and localized pointers or stylus used to digitize intraoperative anatomical landmarks. Both the *Bendini Spinal Rod Bending System* and the predicate device intraoperatively digitize the relative location of anatomical landmarks with a localized pointer or stylus in order to acquire data that is then interpreted by a proprietary set of algorithms.

The main technological differences between the subject *Bendini Spinal Rod Bending System* and the predicate device, K111811, are the following:

- Bendini IR Stylus Handle – modification to incorporate integrated reflective IR markers in a preassembled, sterile, single-use configuration for ease of use. The IR markers used in the predicate Bendini Stylus referenced in 510(k) K111811 were off-the-shelf components.
- Bendini IR Stylus Shaft – modification to a detachable design that attaches to the IR Stylus Handle, and can extend by 2mm increments to add an offset distance to a desired acquisition point.

Any differences in technology do not raise questions or issues regarding safety and effectiveness of the *Bendini Spinal Rod Bending System.*

Based on the comparison above, the subject device was shown to be substantially equivalent and have the same technological characteristics to its predicate device in areas including design, intended use, material composition, and function.

G. Performance Data

Nonclinical testing was performed to demonstrate that the *Bendini Spinal Rod Bending System* is substantially equivalent to a predicate device. This testing performed was determined to be necessary in establishing substantial equivalence and included evaluation of software performance per predetermined specifications outlined in the SRS, GUI functionality, error handling, system accuracy during data acquisition, verification of instrument performance in combination with the software, and verification of software algorithms using anatomical models.

The results of the studies performed show that the subject *Bendini Spinal Rod Bending System* meets the performance of the predicate device, and the subject device was therefore found to be substantially equivalent.

H. Conclusions

Based on the indications for use, technological characteristics, performance testing, and comparison to a predicate device, the subject *Bendini Spinal Rod Bending System* has been shown to be substantially equivalent to the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

NuVasive, Incorporated
% Ms. Sheila Bruschi
Associate Manager, Regulatory Affairs
7475 Lusk Boulevard
San Diego, California 92121

December 7, 2012

Re: K122742
Trade/Device Name: NuVasive® Bendini® Spinal Rod Bending System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: OLO
Dated: November 06, 2012
Received: November 07, 2012

Dear Ms. Bruschi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):_____

Device Name: NuVasive® Bendini® Spinal Rod Bending System

Indications For Use:

The Bendini Spinal Rod Bending System is used to locate spinal implant system instrumentation (screws, hooks) to determine their relative location to one another to generate bend instructions to shape a spinal rod. A surgeon is able to use those instructions and bend a rod using the Bendini Bender, a mechanical rod bender.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Dwight Yen
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(Division Sign-off)
Division of Surgical Devices
510(k) Number K122742